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# Permitting Genetically Engineered Plants That Produce Pharmaceutical Compounds

The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), through its Biotechnology and Regulatory Services (BRS) program, is responsible for regulating the importation, movement, and field release of all genetically engineered (GE) plants—everything from GE grass and trees to food and pharmaceutical crops is covered.

APHIS' biotechnology regulations are designed to ensure that GE plants, such as herbicide-tolerant cotton or virus-resistant papayas, do not pose a significant plant pest risk. BRS involvement begins when a person or organization wishes to move a GE plant. This could involve importing a GE plant, moving one from laboratory to laboratory, or conducting tests outdoors under confinement. To do any of these activities, an authorization from BRS must be obtained. Before approving such an authorization, however, APHIS scientists review relevant scientific data from the required application. There are a number of requirements that must be met before BRS will allow a field test or movement of GE plants. And, for GE plants that produce pharmaceutical compounds, there are additional requirements and conditions needed for an authorization.

## Pharmaceutical Requirements

APHIS issues permits for GE plants that produce compounds intended for pharmaceutical use on a case-by-case basis. APHIS scientists work closely with applicants as well as other biotechnology regulatory authorities, such as the Food and Drug Administration and USDA's Centers for Veterinary Biologics, during the permitting process to ensure that GE plants that produce pharmaceutical compounds don't pose a significant plant pest risk, a risk to threatened and endangered species, or a risk to people working with the GE plants. Specific measures to reduce the risk of harm to other

organisms must be part of any application to ensure GE plants that produce pharmaceutical compounds do not pose a significant plant pest risk. APHIS requires risk mitigation measures as conditions of granting a permit to mitigate any identified risk.

Risk mitigation measures for use during the import, movement and field testing of GE plants include:

- Adequate identification, packaging, and segregation measures to prevent mixing, spillage and dissemination of viable GE plant material;
- Secure greenhouse design that prevents pollen flow outside of the building as well as the flow of fertile GE pollen to sexually compatible plants within the building; and
- Devitalization/disposal of GE plant material by suitable means, when no longer in use or authorized. Means of devitalization/disposal could include, but are not limited to dry heat, steam heat, crushing, deep burial and/or chemical treatment.

In addition to the previous risk mitigation measures, specific mitigation measures must also be in place during field tests. These measures are designed to confine GE plants to the field test site during trials. Risk mitigation measures must also be in place to prevent GE plants or their progeny from persisting in the environment in subsequent growing seasons either inside or outside of the field test site.

During the growing season, measures must be taken to achieve reproductive isolation from plants of the same species and other sexually compatible species. This is to prevent cross pollination with cultivated or wild plants that are not part of the field test. Depending on the plants involved, these measures may include, but are not limited to, one or a combination of the following:

- Netting or bagging of plants during flowering;
- Flower removal prior to pollination;
- Infertile plant lines;
- Isolating plants from sexually compatible plants by distance;
- Different flowering times; and
- Date of termination of the confined field test prior to flowering.

APHIS believes that some plants such as alfalfa and canola are inappropriate for the production of pharmaceuticals. These plants have characteristics like multiple-year seed dormancy, are bee pollinated, and are sexually compatible with weed species in the locality of the field site.

As it has been for the last 15 years, APHIS is committed to ensuring the safe use of agricultural biotechnology. The reorganization of APHIS' biotechnology services into a single program will allow APHIS to strike the proper balance needed for successful regulatory oversight. APHIS scientists work daily to make sure that biotechnology remains safe and poses no significant plant pest risk.

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